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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,959	03/12/2007	Doo Sung Lee	Q96860	5634

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EXAMINER
JONES JR., ROBERT STOCKTON

ART UNIT	PAPER NUMBER
1796	

NOTIFICATION DATE	DELIVERY MODE
01/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,959	LEE ET AL.	
	Examiner	Art Unit	
	ROBERT JONES JR.	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

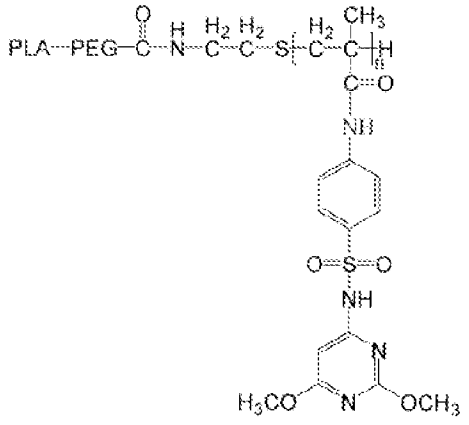
DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han (cited in previous Office Action) in view of Huang (cited in previous Office Action).

3. Regarding Claims 1, 10, and 11, Han teaches a block copolymer comprising poly(ethylene glycol) (PEG), poly(L-lactic acid) (PLA; a biodegradable polymer), and an oligomeric poly(sulfadimethoxine) (PSD; a sulfonamide-based oligomer) formed by coupling a PLA-PEG diblock copolymer with PSD (p. 51, scheme 1, (c)). According to Han's Scheme 1, said PSD possesses a terminal amine group prior to forming the block copolymer. The resulting block copolymer is illustrated below:



PLLA/PEG-PSD

4. Han's block copolymer is effectively a carrier for sulfadimethoxine, a sulfonamide drug. Sulfonamide drugs are chemotherapeutic agents employed for the prevention and cure of bacterial infection (p. 50, col. 1, para. 4). Han does not teach a block copolymer wherein the sulfonamide-based oligomer is coupled to only the biodegradable polymer, or a triblock or higher order multiblock copolymer.

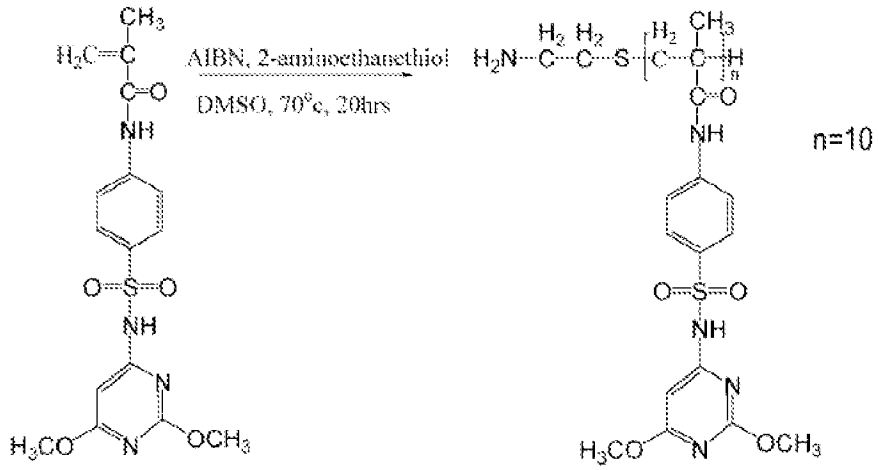
5. In the field of block copolymer-based drug delivery, Huang teaches block copolymers with PEG, PLA, and poly(caprolactone) (PCL) segments (Abstract). PCL is a biocompatible and biodegradable polymer with high permeability to drugs, and additionally possesses a low melting temperature and high decomposition temperature. Thus, PCL has a wide processing range (p. 1, Introduction, lines 8-12). Huang's copolymers conserve the excellent thermal behavior inherent to PCL, thus providing a wide range of processing temperatures for thermal treatments (p. 2000, col. 2, lines 2-6). Huang's copolymers include a pentablock PLA-PCL-PEG-PCL-PLA, and a triblock mPEG-PCL-PLA (mPEG = monohydroxyl poly(ethylene glycol)) (p. 1995, Results and Discussion; p. 1996, Table 1).

6. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Han in view of Huang to replace Han's PEG-PLA copolymer with either Huang's PLA-PCL-PEG-PCL-PLA pentablock or mPEG-PCL-PLA triblock copolymer. Such modification would serve to incorporate one or more PCL blocks into Han's PEG-PLA copolymer, and would result in a lower melting temperature, a higher decomposition temperature, and thus a wider processing range. Additionally, incorporation of PCL will impart PCL's higher permeability to drugs, which is desirable in

view of the fact that Han's copolymer serves as a means of delivery for a sulfonamide drug.

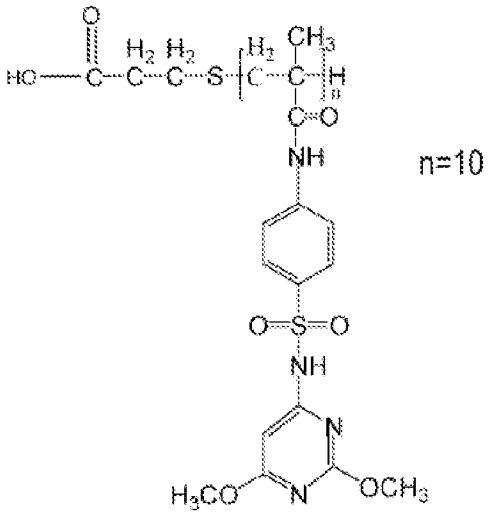
7. Modification of Han in view of Huang would result in a triblock or pentablock copolymer of PEG with two biodegradable polymers (PLA and PCL) and a sulfonamide-based oligomer, wherein the sulfonamide oligomer is coupled to the PLA block and wherein the copolymer and blocks thereof have the characteristics set forth above. Thus, all requirements of Claims 1, 10, and 11 are satisfied.

8. One of ordinary skill in the art will recognize that in order to effectively couple Han's PSD to Huang's triblock or pentablock copolymer, further modification is necessary. Han's Scheme 1 illustrates an amine-functional oligomer, seen here (p. 51, Scheme 1, (b)):

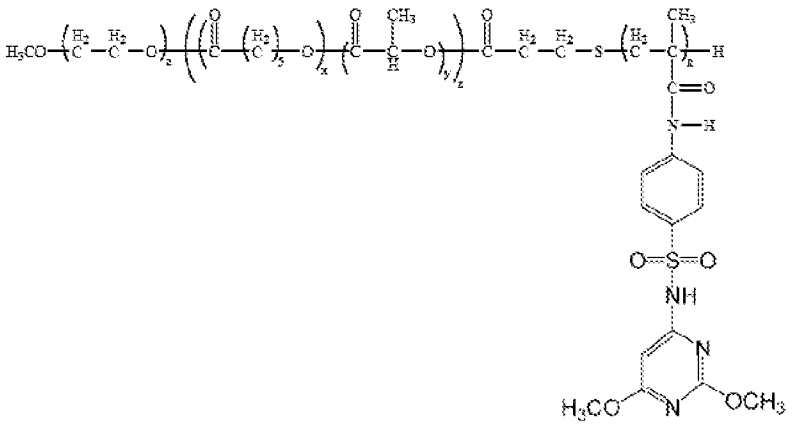


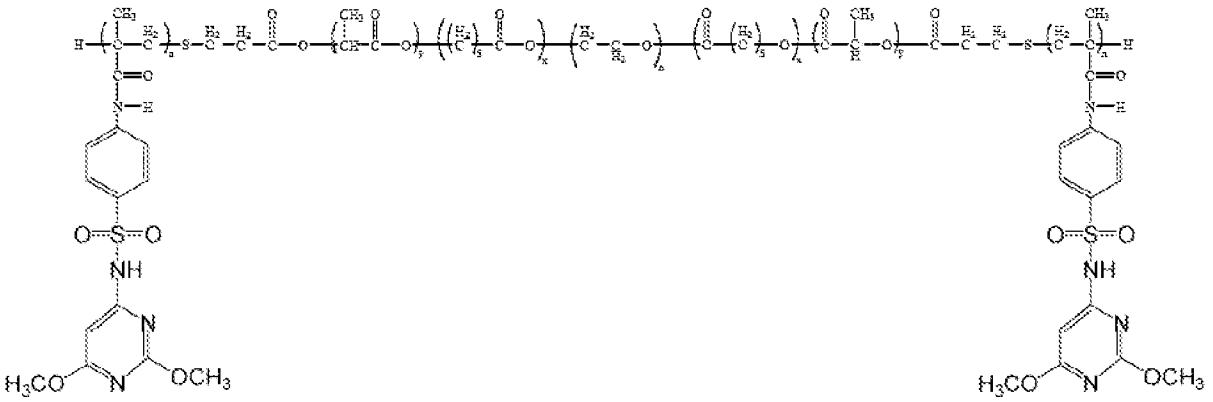
9. However, Huang teaches copolymers comprising PLA end blocks which will inherently be hydroxyl-functional, while Han's PSD is amine-functional. Thus, it is necessary to incorporate an end group into the above PSD that is reactive with a hydroxyl moiety. It is well known that carboxylic acids and their derivatives possess the

desired reactivity. In order to maintain equivalent functionality and retain the 2-carbon chain between the thioether and functional group, one of ordinary skill in the art would at once envisage the use of a mercaptopropionic acid moiety in place of 2-aminoethanol in the scheme above to arrive at the PSD oligomer shown below:



10. In view of the necessary modification to the PSD oligomer, modification of Han in view of Huang will result in the triblock or pentablock copolymers seen here:





11. Regarding Claims 2 and 3, Han's PEG has a molecular weight of 2000 (Claim 3; p. 50, section 2.1). This corresponds to Formula 1 in Claim 2, wherein n=45.

12. Regarding Claims 4 and 5, modification of Han in view of Huang results in a copolymer of PEG with PLA and PCL.

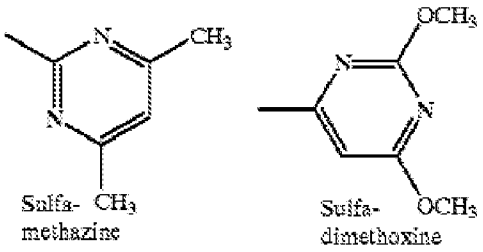
13. Regarding Claim 6, Han's PEG has a molecular weight of 2000, while Han's PLA has a molecular weight of 3500 (p. 52, col. 1, lines 17-18). Thus, the weight ratio of PEG to PLA is 1:1.75 (Claim 6).

14. Regarding Claim 9, in the above formula of Han's sulfonamide oligomer, n is equal to 10. When n=10, the molecular weight of said oligomer is 835 (Claim 9).

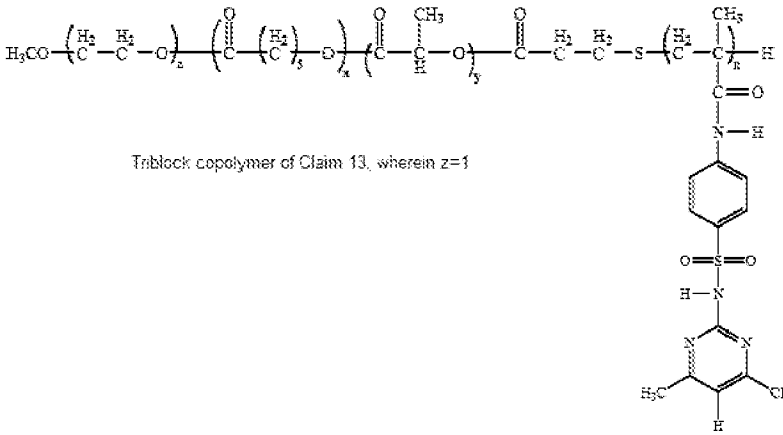
15. Claims 8 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han in view of Huang as applied to claims 1-6 and 9-11 above, and further in view of Bae et al. (cited in previous Office Action).

16. Han in view of Huang remains as applied to Claims 1-6 and 9-11 above. Neither Han nor Huang teach the sulfonamide compound of Claim 8, or copolymers conforming to Formulae 2, 3, and 4 of Claims 12, 13, and 14, respectively.

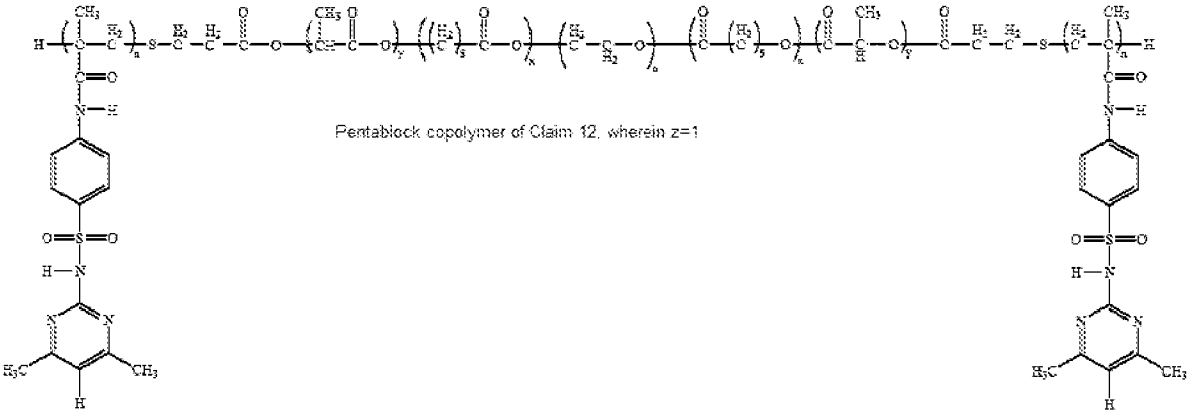
17. In the field of sulfonamide-containing polymers, Bae discloses a number of equivalent sulfonamides (col. 3-4, Table 1). Bae's sulfonamides include sulfadimethoxine and sulfamethazine, illustrated below:



18. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Han in view of Huang as discussed above. It would have been obvious to further modify Han in view of Bae to replace the sulfadimethoxine residue of Han's oligomer with sulfamethazine, as the two are described as alternatives to one another and are functionally equivalent. The resulting modification will yield a pentablock copolymer satisfying the structural requirements of Claim 12, or a triblock copolymer satisfying the structural requirements of Claim 13, illustrated below:

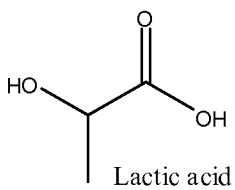


Triblock copolymer of Claim 13, wherein z=1

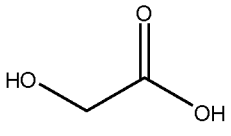


Pentablock copolymer of Claim 12, wherein z=1

19. Regarding Claim 14, neither Han, Huang, nor Bae teach a pentablock copolymer similar to that pictured above wherein the lactic acid residues are replaced with glycolic acid residues. Lactic and glycolic acids have the structure seen below:



Lactic acid



Glycolic acid

The two differ by a single carbon, are functionally equivalent, and it is well known and established in the art that both polylactic acid and polyglycolic acid are biodegradable.

Thus, lactic acid and glycolic acid are considered to be structurally similar, differing by a methyl group only.

20. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the pentablock copolymer resulting from Han in view of Huang and Bae to replace the PLA segment with a polyglycolic acid segment, as the two are structurally similar and therefore functional equivalents. Using glycolic acid instead of lactic acid would still provide biodegradable polymer that can be utilized in the same manner as that of Han.

21. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han in view of Huang as applied to Claims 1-6 and 9-11 above, further in view of Shah (cited in previous Office Action).

22. Regarding Claims 15 and 16, Han remains as applied above. Han does not teach a hydrogel composition comprising a block copolymer as claimed in any one of Claims 1-6 and 8, or a hydrogel formed from said hydrogel composition.

23. In the field of biodegradable block copolymer-based drug delivery, Shah teaches forming hydrogels from block copolymers comprising PLA or poly(lactide-co-glycolide) (PGLA) and PEG, for the sustained delivery of biologically active agents (Abstract). Shah further teaches that biodegradable block copolymers formed from PEGs with molecular weights ranging from 200 to 2000, and PLA or glycolic acid (GA) with molecular weights ranging from 400 to 5000 formed hydrogels (col. 2, line 67 – col. 3, line 3).

24. It would have been obvious to one of ordinary skill in the art at the time of the invention to form a hydrogel comprising Han's PLA-PEG-sulfonamide for the benefit of providing sustained release for the sulfonamide-based drug portion of the molecule. Said hydrogel is also intrinsically a hydrogel composition.

Response to Arguments

25. Applicant's arguments with respect to claims 1-6 and 8-16 have been considered but are moot in view of the new ground(s) of rejection.

26. The Applicant argues that contrary to the amended claims, Han's sulfonamide-based oligomer is bound to PEG rather than to the biodegradable polymer segment. This deficiency in Han is addressed in the new grounds of rejection presented above.

27. The Applicant further asserts that Han's copolymer cannot achieve "the effect of hydrogel formation according to the autonomous sol-gel transition" attained by the claimed invention. This characteristic is not included in the instant claims. The discussion and illustrations presented on p. 9-11 appear to be an assertion of unexpected results. The Applicant is reminded that unexpected results must be established by factual evidence. Due to the absence of tests comparing appellant's block copolymer with those of the closest prior art, it is concluded that the Applicant's assertions of unexpected results constitute mere argument. See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984); In re Lindner,

457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

28. Furthermore, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include, inter alia, statements regarding unexpected results. MPEP 716.01(c).

Conclusion

29. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSJ

/David Wu/
Supervisory Patent Examiner, Art Unit 1796